



MAR - 9 2005

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Re: Patent Term Extension
Application for
U.S. Patent No. 5,194,247

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,194,247, which claims the drug product SOLAGE® (Mequinol), and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,365 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,365 days.

If the period of extension were to be calculated under 35 U.S.C. § 156(c) using the Food and Drug Administration's determination of the length of the regulatory review period, as published in the Federal Register of November 14, 2002 (67 Fed. Reg. 69016), the period of extension would be as follows:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,978 - 228) + 711 \\ &= 1,586 \text{ days}\end{aligned}$$

Since the regulatory review period began August 1, 1992, before the patent issue date (March 16, 1993), the entire period from August 1, 1992 until and including March 16, 1993 is subtracted from the "Testing Phase" in the above calculation. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,586 days, would extend the patent from March 16, 2010 (35 U.S.C. § 154) to July 19, 2014, which is beyond the 14-year limit (the approval date is December 10, 1999, thus the 14 year limit is December 10, 2013). The period of extension is thus limited to December 10, 2013, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 16, 2010, to and including December 10, 2013, or 1,365 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No. 5,194,247

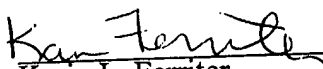
U.S. Patent No.:	5,194,247
Granted:	March 16, 1993
Applicant:	Xina Nair, et al.
Owner of Record:	Galderma S.A.
Title:	Synergistic Skin Depigmentation Composition
Classification:	424/59
Product Trade Name:	SOLAGE® (Mequinol)
Term Extended:	1,365 days
Expiration Date of Extension:	December 10, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7744

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.


Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: SOLAGE® (Mequinol)
FDA Docket No.: 02E-0022

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